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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,540	09/05/2003	Steve Koh	A03P1060	8767
36802	7590	05/18/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			FLORY, CHRISTOPHER A	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary

Application No.

10/656,540

Applicant(s)

KOH ET AL.

Examiner

Christopher A. Flory

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 10-14, 19, 20, 22, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 15-18, 21, 23, 24 and 26 is/are rejected.
- 7) ☒ Claim(s) 7-9 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/05/03 & 12/08/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. During a telephone conversation with Derrick Read on 26 April 2006, a provisional election was made without traverse to prosecute the invention of embodiment I represented by determining a respiratory characteristic from A-V conduction intervals, claims 1-9, 15-18, 21, and 23-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-14, 19, 20, 22, 27 and 28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 256 in Figure 2 and 500 in Figure 5. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

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informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 involves the step of determining whether the respiratory characteristic indicates apnea. Claim 7, dependent from claim 6, discriminates between obstructive apnea and central apnea based on the determination in claim 6. Therefore, the limitation of claim 9 that the discrimination between obstructive and central apnea rely on a known respiratory characteristic has already been met by the phrasing of claims 6 and 7, which inherently conclude that you use a respiratory characteristic to indicate apnea and discriminate between the two stated forms.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1, 4, 5, 15, 17, 21, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Thornander et al. (US Patent 4,712,555).

Regarding claims 1 and 15, Thornander et al. discloses a method comprising delivering one or more pacing pulses to an atrium (ABSTRACT; column 2, line 67 through column 3, line 7); determining one or more atrioventricular conduction interval times based on the pacing pulses (ABSTRACT; column 3, lines 37-45); and determining a respiratory characteristic based at least in part on the AV conduction interval times (**column 21, line 65 through column 22, line 10; column 23, lines 7-8; column 2, lines 47-51; column 3, lines 20-30; column 3, lines 65-68**).

It is noted that increased workload and changes in heart rate as disclosed in Thornander et al. are being understood as respiratory characteristics, because increased workload (i.e. exercise) produces an increased respiratory frequency, while it is known that heart rate is an indicator of respiratory state, since inhalation raises the instantaneous heart rate slightly, while exhalation decreases instantaneous heart rate.

Regarding claim 4, Thornander et al. discloses that the atrial pacing occurs at a rate that varies with respect to an intrinsic rate (ABSTRACT; column 2, line 47 through column 3, line 6).

Regarding claim 5, the pacemaker of Thornander et al. varies the atrial pacing rate in response to intrinsic rates that change over a given time period based on increased or decreased physiologic demands. Because the rates on which the pacing is based vary with respect to time, the atrial pacing rate can also be said to vary with

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respect to time. Therefore, the claim limitation of the instant claim does not distinguish over the prior art.

Regarding claims 21, 23 and 26, Thornander et al. shows an implantable cardiac stimulation system (Fig. 10, pacemaker 16) comprising sensing circuitry operative to sense atrial and ventricular events (P-wave sense/pace amp 48, R-wave sense/pace amp 56); a processor connected to the sensing circuitry (Fig. A-1, microprocessor 408) operative to determine one or more A-V conduction interval times based on the delivered stimulation pulses (ABSTRACT; column 3, lines 37-45) and further operative to determine a respiratory characteristic based at least in part on the A-V interval times (column 21, line 65 through column 22, line 10; column 23, lines 7-8; column 2, lines 47-51; column 3, lines 20-30; column 3, lines 65-68); and further comprising a pulse generator operative to generate stimulation pulses for delivery to a patient's heart (Fig 10, pulse generator logic 42 and pulse output driver circuits 44 connected to heart 18), and at least one electrode (atrial lead 22 with tip electrode 24; ventricle lead 30 with electrode 46).

5. Claims 15-16, 21, 23, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lurie et al. (US Patent 5,919,210).

Regarding claims 15 and 16, Lurie et al discloses a method comprising determining one or more A-V conduction interval times and determining a respiratory characteristic based at least in part on the one or more conduction interval times (ABSTRACT; column 2, lines 24-38; Figures 3-6); wherein the respiratory characteristic comprises a respiratory cycle length (column 2, line 31—respiration rate is being taken

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by definition to be a well-known mathematical equivalent to respiratory cycle length, because a patient with a respiration rate of 10 breaths per minute has with mathematical certainty a respiratory cycle length of 6 seconds).

Regarding claims 21, 23 and 26, Lurie et al. shows an implantable cardiac stimulation system (Fig. 1, device 10) comprising sensing circuitry (sense amp 36, lead 12); a processor connected to the sensing circuitry (microprocessor 22); and further comprising a pulse generator (pacing pulse generator 38), and at least one electrode connected to the pulse generator (electrodes 14 on heart 16).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 6, 16, 18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thornander et al. in view of Cho et al. (US Patent 6,641,542).

Thornander et al. discloses the instant invention substantially as claimed except that the respiratory characteristic comprises a respiratory cycle length and determining whether the respiratory characteristic indicates apnea. Cho et al. teaches a cardiac pacemaker that uses average respiration cycle length for detecting sleep apnea (ABSTRACT, column 3, lines 10-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as

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taught by Thornander et al., with detecting respiratory cycle length as taught by Cho et al., since such a modification would provide the system with an alternate means for providing detection of sleep apnea (motivation to combine provided by Cho et al., column 3, lines 10-25).

8. Claims 18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lurie et al. in view of Cho et al.

Lurie et al. discloses the instant invention substantially as claimed except for determining whether the respiratory characteristic (respiratory cycle length) indicates apnea. Cho et al. teaches using average respiration cycle length for detecting sleep apnea (ABSTRACT, column 3, lines 10-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Lurie et al., with detecting respiratory cycle length as taught by Cho et al., since such a modification would provide the system with the ability to detect sleep apnea (motivation to combine provided by Cho et al., column 3, lines 10-25).

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thornander et al. in view of Applicant's own admitted prior art (Admission).

Thornander et al. discloses the instant invention substantially as claimed but does not expressly state that atrial pacing occurs at a frequency that is at least double the respiratory frequency. Admission teaches that according to signal sampling theory, the sampling frequency must be greater than twice the maximum frequency of the sampled behavior in order to sufficiently avoid frequency aliasing (paragraph [68]). In this case, this theory applies in that the AV Interval, which represents the sample of the

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respiratory characteristic, must be calculated at greater than double the frequency of the respiratory cycle, which inherently means that atrial pacing must occur at double the respiratory frequency (because one AV Interval is sampled for each atrial pacing pulse delivered). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system disclosed in Thornander et al., with the pacing frequency of at least double the respiratory frequency in Admission, for the advantage of avoiding frequency aliasing and the resultant of improper determination of the respiratory characteristic (motivation to combine provided by Admission, paragraph [68]).

Allowable Subject Matter

10. Claims 7-9 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

12 May 2006


George Manuel
Primary Examiner